

**Testimony of Celeste Monforton, MPH, DrPH**  
**before the U.S. House of Representatives**  
**Committee on Education and Labor**  
**Subcommittee on Workforce Protections on the**  
**“Impact of Department of Labor’s Worker Health Risk Assessment Proposal”**

September 17, 2008

Chairwoman Woolsey and Members of the Subcommittee:

I am Celeste Monforton, a researcher in the Department of Environmental and Occupational Health at the George Washington University School of Public Health & Health Services. I appreciate the opportunity to appear before the subcommittee to share my views on the Department of Labor’s proposed rule on MSHA and OSHA risk assessment procedures for occupational health hazards.<sup>1</sup>

On its face, I understand how some individuals might ask “who could be against the Labor Department having requirements for risk assessment?” In fact, this proposal is so potentially damaging to worker health that 80 epidemiologists, physicians, and other health scientists,<sup>2</sup> including the American Public Health Association,<sup>3</sup> urged the Secretary of Labor to withdraw her plan to issue a regulation on how occupational health risks are assessed.

I am currently preparing my detailed written comments on the proposed rule, which I plan to submit to the Labor Department by the September 29 deadline, but I am pleased to share my big-picture concerns about it, concerns that are shared by other public health scientists and proponents of health-protective standards for working men and women in our country.

Our nation’s system for protecting workers from harmful substances that cause injuries, illnesses, and deaths is paralyzed. Thousands of workers are exposed every day to chemical compounds and physical hazards that are known to be harmful, yet these exposures are permitted by outdated or non-existent OSHA and MSHA standards. Hazards such as respirable coal mine dust and crystalline silica, diesel particulate, and noise,<sup>4</sup> to name just a few, have damaged the health of generations of workers and continue to do harm today – even though we have known about these problems for decades.

The Department of Labor’s record over the last 20 years is dismal with respect to issuing health standards to protect workers from these age-old contaminants, and it is particularly appalling for emerging health hazards. The overwhelming majority of the permissible exposure limits currently on OSHA’s and MSHA’s books date back to 1968 and 1973, respectively. These current limits are based on science from the 1960’s, meaning the last 40-50 years of scientific understanding of how chemicals affect human health are not reflected in most OSHA or MSHA standards.<sup>5</sup> For many of these compounds, the health science data suggests that the existing permissible exposure limits should be amended if we want to

reduce workers' risk of adverse health effects. As the former chair of this subcommittee, the late Congressman Charlie Norwood, acknowledged, there are many OSHA standards that are out of date and need to be updated in order to achieve safe and healthful workplaces for American workers.<sup>6</sup> It should be a grave concern to all of us, no matter what our political views, that the promise of the OSH Act and the Mine Act is not being upheld for workers who are made ill due to harmful on-the-job exposures.

While we know of many as-yet-unregulated workplace hazards, there are likely many others that we will become aware of in the future. There are 82,000 chemicals listed in U.S. EPA's TSCA inventory,<sup>7,8</sup> of which nearly 3,000 are compounds manufactured or imported annually in quantities greater than 1 million pounds, and another 6,000 compounds used in quantities between 10,000 and just below 1 million pounds.<sup>9</sup> Many of these chemical compounds, especially in their final form, have improved our way of life. We must also recognize, however, that under current workplace standards, we have no systematic way to monitor the exposure of workers who manufacturer or work downstream with these thousands of compounds, nor do we have a mechanism to assess the adverse health consequences that may be associated with exposure to them individually or in combination with other chemicals.

The public health and workers' rights communities would have welcomed a Department of Labor effort to improve the efficiency and effectiveness of the rulemaking process, or even to address one of the many hazards that continue to put workers' lives and health at risk. Instead, the Labor Department is sponsoring changes that will further paralyze the rulemaking process. Future OSHA and MSHA administrators who may be more inclined to pursue new standards to protect workers from harmful exposures will find themselves facing new obstacles. These obstacles mean additional months and years of exposure for workers, during which some of them will develop life-threatening conditions.

### **Standard-Setting under MSHA and OSHA: Prevention-Based Statutes**

The Mine Act of 1977<sup>10</sup> and the OSH Act of 1970<sup>11</sup> are robust, well-crafted statutes that give broad authority to the Secretary of Labor to regulate workers' exposure to toxic materials, and were clearly grounded in the public health principle of **prevention**. The overarching goal of both statutes was to identify, mitigate, and/or control hazards **before** they cause harm. Both statutes include the following prevention framework:

“The Secretary, in promulgating standards dealing with toxic materials...shall set the standard...that no employee will suffer material impairment of health...even if the employee has regular exposure to the hazard...for the period of his working lifetime.”<sup>12</sup>

It might be worthwhile to explain how risk assessment informs the Department of Labor's standard-setting process, but first let's simply review what “risk assessment” is. The term “risk assessment” has a variety of meanings depending on the context of the “risk” and the

perspective of the assessor. Risk assessments are conducted by investors in the financial markets, by fire chiefs in command centers during emergency response, and by environmental scientists trying to estimate the impact of a commercial development on the habitat of a native species. They may rely on quantitative data, qualitative data, or both.<sup>13</sup> In the simplest terms, a risk assessment is the process of using the best information available to describe or estimate the risk of an adverse event. A risk assessment is a decisionmaking tool that allows users to make informed decisions; it does not dictate what the final decision will be.

In the context of occupational health standards, a risk assessment is prepared by OSHA to determine if exposure to a toxic material poses a significant risk to workers.<sup>14</sup> If the hazard does not pose a significant risk, the agency does not have the authority to regulate it. OSHA is required to make a significant-risk finding which, based on the U.S. Supreme Court's 1980 suggestion<sup>15</sup>, is a risk of about 1 in 1,000. This means that when there is evidence that a particular substance is causing harm to workers, OSHA will gather the best available information to estimate if workers exposed to the substance face a higher risk of harm compared to individuals who are not exposed. If, for example, the epidemiological evidence suggests that for every 1,000 exposed workers, at least 6 excess cases of bladder cancer will occur, this information provides OSHA with its finding of "significant risk." On the other hand, if the available evidence suggests that the number of excess cases of bladder cancer is 1 out of 5,000 workers, then this estimate would not meet the threshold finding of a significant risk. For OSHA, the written output of using the available evidence to characterize the exposed workers' risk is the agency's "risk assessment."

Since the 1980's, when the Labor Department began preparing quantitative risk assessments to support health standards for toxic substances, the agency's assessments have consistently withstood vigorously scientific scrutiny and legal challenges. Whether the contaminant regulated was asbestos, lead, vinyl chloride, formaldehyde, butadiene, or diesel particulate matter, the assessments have been based on the best available evidence and determined, with little room for doubt, that the levels of exposure experienced by workers placed them at significant risk of "material impairment of health or functional capacity."<sup>16</sup>

We must remember that risk assessments are not the only factors in regulatory decisions; OSHA and MSHA must also conduct economic analyses and ensure that their regulations are economically and technologically feasible. This means that even if the agency's risk assessment for chemical X suggests that an exposure limit should be set at Y in order to protect workers from disease (e.g., lung cancer, lead poisoning,) the agency has to set the exposure limit as a level that is feasible. This might mean an exposure limit of Y\*2, Y\*5, or whatever level is determined feasible. The permissible exposure limits incorporated into OSHA standards are driven by a combination of the risk assessments and the feasibility data.

If the Department of Labor is spending its finite resources on this risk assessment proposal it ought to be in response to a critical flaw in the current risk assessment process. No

evidence is presented in the preamble to this proposed rule (or elsewhere, to my knowledge) to suggest fundamental flaws in OSHA's or MSHA's risk assessment practices.

### **DOL's Rationale Based on Misreading of 1997 Commission Report**

The rationale DOL gives for this proposed rule, both in the document itself and in statements made by Department officials, is largely based on a misreading of a recommendation made more than 11 years ago in a report by a Presidential/Congressional Commission.<sup>17</sup> The Department has cherry-picked a single sentence from the Commission's report and ignores its key recommendation. The part of the 1997 Commission report DOL seizes on says that:

“OSHA seems to have relied upon a case-by-case approach for performing risk assessment and risk characterization in support of risk management policy decisions.”

This phrase “case-by-case approach,” is conveniently described by the Labor Department as a “criticism,”<sup>18</sup> although the 1997 report never labels it that way. What DOL fails to mention in its proposal is the specific recommendation from the Commission's report, which states:

“**OSHA** should publish, **after appropriate public involvement and review, one or more sets of guidelines that lay out its scientific and policy defaults.** At a minimum, the guidelines should cover an explicit rationale for choosing the defaults and an explicit standard for how and when to modify them; methods for assessing risk for noncancer health effects of concern in occupational settings; methods for quantifying and expressing uncertainty and individual variability in risk; and a statement of the magnitude of individual risk that it considers negligible for the various adverse health effects. The guidelines should help OSHA decide how extensive a risk assessment is needed in different situations. Finally, OSHA should explain and justify its actions when it evaluates or regulates a substance differently than other federal agencies that regulate the same substance.”<sup>19</sup>

Note that the Commission's recommendation was for OSHA to develop guidelines, not some other office within DOL that does not have experts in epidemiology, biostatistics or other health sciences, or experience preparing risk assessments on workplace chemical hazard exposure and health effects. An appropriate question for this committee to explore is determining the extent of involvement, if any, of the career federal employees at MSHA and OSHA in the development of this proposal. These individuals are the most expert at preparing occupational health risk assessments and would be best able to identify the agencies' best practices<sup>20</sup>

Other substantive parts of the 1997 Commission's recommendation are curiously absent from DOL's proposal, such as the suggestions to:

- do more to address non-cancer health effects (e.g., cardiovascular, cardiopulmonary, neurological, reproductive)
- do more to address individual variability (e.g., protection factors for susceptible subpopulations)
- develop guidelines with sufficient flexibility to allow for different types of risk assessments depending on the nature of the hazard

If the DOL had truly paid attention to the Commission’s recommendations rather than focusing on a single sentence and misinterpreting that sentence as a criticism, its risk-assessment proposal would have looked very different.

### **DOL’s Disregard for 2007 National Academies’ Report**

Even more troubling than misreading the 1997 Commission’s report is the Department’s disregard for the much more recent 2007 report the National Research Council of the National Academies entitled “Scientific Review of the Proposed Risk Assessment Bulletin from the Office of Management and Budget.” This report offered a harsh critique of the White House Office of Management and Budget’s proposed risk assessment guidelines, including the conclusion that OMB’s product was “fundamentally flawed.”<sup>21,22</sup> In the NRC’s report, the scientific committee recommended to OMB that any risk assessment guidance documents prepared by the Administration:

“outline goals and general principles of risk assessment designed to enhance the quality, efficiency, and consistency of risk assessment...[that would] be consistent with each agency’s legislative mandates and missions, and draw on the expertise that exists in federal agencies and other organizations. The technical guidance developed by or identified by the agencies should be peer-reviewed and contain procedures for ensuing agency compliance with the guidance.”<sup>23</sup>

The Department of Labor has failed to fulfill this recommendation by neglecting to:

- “outline goals and general principles of risk assessment”;
- develop guidelines that would “enhance the quality, efficiency and consistency of risk assessment”;
- “draw on the expertise in federal agencies and other organizations”; and
- subject the proposed rule to “peer review”

I would respectfully request Chairwoman Woolsey or other members of the subcommittee to ascertain from Assistant Secretary Sequeira why this proposed rule on risk assessment does not meet the standards recommended just last year by the National Academies’ panel.

## **“Best Practices”: Missing in Action in DOL’s Proposed Rule**

There is a fundamental disconnect between what the Department of Labor says about this proposed rule and their actions.

### **1) Their timing discourages the input they claim to value**

First, the proposed rule says they are seeking public comment

“...in order to gain valuable public input and in the interests of full transparency and accountability.”<sup>24</sup>

Yet, the time allowed to submit written comments is only 30 days (the deadline is September 29), hardly consistent with the Department’s claim of wanting to receive “valuable public input.” Similarly, Secretary Chao’s spokesperson said the public would “have plenty of opportunity”<sup>25</sup> to examine and debate the proposal. It is hard to believe he actually thought that a robust debate could occur in such a short time span.

### **2) They made a feeble attempt to compile OSHA’s actual best practices**

The preamble to the proposed rule suggests that the regulation is simply about assembling the Department’s “best practices” for risk assessment into a single document. OSHA has nearly 30 years of history developing risk assessments, and had the Department truly wanted to compile the agency’s “best practices” it could have evaluated methodically the scientific assumptions, controversies, and other issues encountered by OSHA and MSHA over the years. In DOL’s proposed rule, however, one will find very little in the regulatory text that could be characterized as a “best practices.” Instead the proposal offers the most elementary definitions of “hazard identification,” “dose-response assessment,” and “exposure assessment,” and completely neglects to mention the Department’s own five-page appendix issued in 2002 under its Information Quality Guidelines describing procedures to be used by OSHA and MSHA when conducting risk analyses for health and safety rules.<sup>26</sup> Likewise, the news release issued by the Department stated “the department does not have comprehensive regulations or formal internal guidance outlining consistent risk assessment procedures,”<sup>27</sup> again, forgetting about its written procedures already on the books.

### **3) They describe the ANPRM as a best practice when it is not**

While overlooking practices developed by OSHA and MSHA experts over the past several decades, the Department’s proposal identifies one practice that it identifies erroneously as a “best practice”: Advanced notice of proposed rulemaking (ANPRM). The Department offers no evidence to support its assertion that ANPRM represents a best practice for risk assessment. To the contrary, I would suggest that that available data indicates that adding the mandatory step of an ANPRM delays significantly the completion of a standard to protect workers’ health. In the case of OSHA’s rule on butadiene, the agency issued an

ANPRM in 1986 and the final rule was not completed until 1996. For methylene chloride, OSHA published an ANPRM in 1986 and the final rule was issued in 1997. In contrast, OSHA's did not issue an ANPRM for hexavalent chromium, it proposed a rule in 2004 and the final was issued in 2006. Likewise, MSHA proposed its diesel particulate matter rule in 1998 and completed it in January 2001. I suppose a "best practice" is in the eyes of the beholder. If the objective is to delay health protective rules as long as possible, an ANPRM would be a "best practice." But for the workers who are exposed to a hazardous substance and whose health would be protected by a workplace standard, the extra years of delay associated with an ANPRM are anything but a best practice. There are costs associated with such delays, costs in terms of additional years of exposure and harm incurred.

#### **4) They fail to follow their own proposed rule for posting documents promptly**

In its proposed rule, DOL is requiring MSHA and OSHA to post all relevant documents at Regulations.gov within 14 days of each key steps in the rulemaking process (e.g., issuing a proposed rule). As of September 15, 2008 (17 days after DOL's proposed rule was published in the *Federal Register* – and more than halfway through the comment period) the Department has not yet posted any supporting documents or background materials in the public docket for this rule.<sup>28</sup> The double standard is striking.

The Department of Labor's entire process for developing and issuing the proposal has disregarded recent reports and decades of MSHA and OSHA practices, while ignoring the standards of openness and transparency that the Department claims to value. Most distressing, however, is the content of the rule. The Department of Labor is proposing changes to MSHA's and OSHA's risk assessment procedures that will impede, not improve, health protections for workers. It is imperative that this Committee use its oversight role to ensure that the promises of the OSH Act and the Mine Act are upheld for the sake of our nation's workers – the individuals who create the wealth for businesses and our entire country.

## **REFERENCES**

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<sup>1</sup> U.S. Department of Labor, Assistant Secretary for Policy. "Requirements for DOL Agencies' Assessment of Occupational Health Risks," (RIN: 1290-AA23), 73 *Federal Register* 50909, August 29, 2008.

<sup>2</sup> Letter from scientists to Secretary of Labor Elaine Chao, August 14, 2008, (Attachment A)

<sup>3</sup> Letter from Georges Benjamin, MD, Executive Director, American Public Health Association, to Secretary of Labor Elaine Chao, August 12, 2008 (Attachment B)

<sup>4</sup> The gaps in worker protections for well known hazards are glaring. Neither OSHA nor MSHA have comprehensive occupational health standards to protect workers from respirable coal mine dust or respirable crystalline silica. In 1974 NIOSH recommended an exposure limit for silica of 0.05 mg/m<sup>3</sup> (for up to a 10-hr workday during a 40-hr workweek)

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[National Institute for Occupational Safety and Health, U.S. Department of Health, Education and Welfare. "Criteria for a recommended standard: occupational exposure to crystalline silica," 1974] and reiterated this recommendation in 2002 [National Institute for Occupational Safety and Health, U.S. Department of Health and Human Services, "NIOSH Hazard Review: Health Effects of Occupational Exposure to Respirable Crystalline Silica," 2002.] In 1995, NIOSH recommended that coal miners' exposure to respirable coal mine dust be reduced from 2 mg/m<sup>3</sup> to 1 mg/m<sup>3</sup> (time-weighted concentration for up to 10 hours/day) [National Institute for Occupational Safety and Health, U.S. Department of Health and Human Services, "Criteria for a recommended standard: occupational exposure to respirable coal mine dust," 1995] yet the outdated standard remains on MSHA's books. A comprehensive OSHA standard to protect many workers from noise-induced hearing loss was issued in 1983, but there is no equal health protection for construction workers. In January 2001, MSHA issued a health standard to protect underground mine workers from exposure to diesel particulate matter (which is associated with cardiovascular and cardiopulmonary disease, and lung cancer,) but workers in all other industries (e.g., industrial operations, construction sites, bus/truck depots and repair platforms, shipyards and ports, etc.) are not protected adequately from this hazardous exposure.

<sup>5</sup> Occupational Safety and Health Administration, U.S. Department of Labor. Air contaminants proposed rule. 53 *Federal Register* 20960, June 7, 1988; 30 Code of Federal Regulations, Subpart D: Air quality and physical agents, 56.5001.

<sup>6</sup> The Honorable Charlie Norwood, Opening Statements at hearings of the Subcommittee on Workforce Protections: "Making Sense of OSHA Rulemaking: A Thirty Year Perspective," June 14, 2001; "The Role of Consensus Standard Setting Organizations," November 1, 2001; "Can a Consensus be Reached to Update OSHA's PELs," July 16, 2002.

<sup>7</sup> A list maintained by EPA based on submissions from manufacturers which provides information on chemicals in commerce, called the TSCA inventory, referring to the Toxic Substances Control Act of 1976 which authorized EPA to collect this information.

<sup>8</sup> U.S. General Accountability Office. "Chemical Regulation: Comparison of U.S. and Recently Enacted European Union Approaches to Protect against the Risks of Toxic Chemicals," Report No. GAO-07-825, August 2007.

<sup>9</sup> Lowell Center for Sustainable Production, University of Massachusetts, Lowell. "The Promise and Limits of the United States Toxic Substances Control Act," October 2003. Available at: [www.chemicalspolicy.org/downloads/Chemicals\\_Policy\\_TSCA.doc](http://www.chemicalspolicy.org/downloads/Chemicals_Policy_TSCA.doc)

<sup>10</sup> 29 U.S.C. §651

<sup>11</sup> 30 U.S.C. §801, *et seq*

<sup>12</sup> Section 6(b)(5) of the Occupational Safety and Health Act of 1970 (29 U.S.C. §651), and Section 101(a)(6)(A) of the Federal Mine Safety and Health Act of 1977 (30 U.S.C. §801, *et seq*).

<sup>13</sup> In 1983, the National Research Council issued the legendary "Red Book," which defined [chemical] risk assessment as "the qualitative or quantitative characterization of the potential health effects of particular substances on individuals or populations." National Research Council. *Risk Assessment in the Federal Government: Managing the Process*. 1983.



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<sup>14</sup> Under the U.S. Supreme Court’s decision in *Industrial Union Department v. American Petroleum Institute*, [448 U.S. 607 (1980)], OSHA is required to find “as a threshold matter, that the toxic substance in question poses a significant health risk in the workplace and that a new, lower standard is therefore ‘reasonably necessary or appropriate’ to provide safe or healthful employment and places of employment.”

<sup>15</sup> *Industrial Union Department v. American Petroleum Institute*, 448 U.S. 607 (1980).

<sup>16</sup> Section 6(b)(5) of OSH Act.

<sup>17</sup> The Presidential/Congressional Commission on Risk Assessment and Risk Management. “Risk Assessment and Risk Management in Regulatory Decision-Making.” Final Report, Vol. 2, 1997.

<sup>18</sup> OSHA News Release. “Notice of Proposed Rulemaking on U.S. Department of Labor’s risk assessment procedures published in Federal Register,” Release Number: 08-1242-NAT, 08/29/2008.

<sup>19</sup> The Presidential/Congressional Commission on Risk Assessment and Risk Management. “Risk Assessment and Risk Management in Regulatory Decision-Making.” Final Report, Vol. 2, 1997. (p. 133-134)

<sup>20</sup> The proposal also fails to mention the comprehensive report prepared by the National Advisory Committee on Occupational Safety and Health which was commissioned precisely to examine and make recommendations on OSHA’s standards development process. The report was released on June 6, 2000.

<sup>21</sup> National Research Council of the National Academies. “Scientific Review of the Proposed Risk Assessment Bulletin from the Office of Management and Budget,” 2007.

<sup>22</sup> National Academies. News Release: “Report Recommends Withdrawal of OMB Risk Assessment Bulletin,” January 11, 2007.

<sup>23</sup> The Presidential/Congressional Commission on Risk Assessment and Risk Management. “Risk Assessment and Risk Management in Regulatory Decision-Making.” Final Report, Vol. 2, 1997. (p. 105)

<sup>24</sup> U.S. Department of Labor, Assistant Secretary for Policy. “Requirements for DOL Agencies’ Assessment of Occupational Health Risks,” (RIN: 1290-AA23), 73 *Federal Register* 50909, August 29, 2008, at 50910.

<sup>25</sup> Lewis R. Bush Administration Tries To Slow Workplace Toxin Rules. ProPublica, July 23, 2008. At: <http://www.propublica.org/article/bush-administration-tries-to-slow-workplace-toxin-rules-723/>

<sup>26</sup> U.S. Department of Labor. “Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Department of Labor,” October 1, 2002.

<sup>27</sup> OSHA News Release, Release Number 08-1242-NAT, 08/29/2008.

<sup>28</sup> Public docket available at <http://www.regulations.gov>

August 14, 2008

The Honorable Elaine Chao  
Secretary of Labor  
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By fax: 202-693-6111  
and regular mail

Dear Secretary Chao:

We are writing to urge you to withdraw the proposed rule “Requirements for DOL Agencies’ Assessment of Occupational Health Risks” (RIN 1290-AA23), which is pending review at the Office of Management and Budget’s (OMB) Office of Information and Regulatory Affairs. The proposed rule fails to provide any validated guidance that would improve the current risk assessment approaches used by MSHA and OSHA, and has serious flaws that would weaken current procedures and undermine occupational health rules. Furthermore, the draft proposal would add an additional step to the rulemaking process, further delaying the development and issuance of needed health and safety protections for workers.<sup>1</sup>

If the Department of Labor (DOL) is serious about improving its risk assessment approaches, it should be guided by recommendations of the National Academies’ National Research Council (NRC) and other authoritative bodies, rather than a scattered approach that fails to incorporate advice from agency experts, practitioners, worker advocates, and the public.<sup>2</sup> The NRC panel charged with reviewing the 2006 OMB Risk Assessment guidelines issued its scathing report in January 2007, concluding “that the OMB bulletin is fundamentally flawed” and recommending that “it be withdrawn.”<sup>3</sup> Nonetheless, many of the faulty OMB recommendations have re-emerged in this DOL proposal.

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<sup>1</sup> Original documents and chronology of events can be accessed at:  
[http://www.defending-science.org/case\\_studies/Secret-DOL-Rule.cfm](http://www.defending-science.org/case_studies/Secret-DOL-Rule.cfm).

<sup>2</sup> The National Research Council (NRC) Report, *Scientific review of the proposed risk assessment bulletin from the Office of Management and Budget* (2007), pointed out that, “the major recommendations that have emerged from nearly 25 years of study of risk assessment have much in common”, including the following: the *Red Book* (NRC, 1983); *Science and Judgment in Risk Assessment* (NRC, 1994); *Understanding Risk: Informing Decisions in a Democratic Society* (NRC, 1996), and *Review of the Proposed OMB Risk Assessment Bulletin* (NRC, 2007).

<sup>3</sup> NRC. *Scientific review of the proposed risk assessment bulletin from the Office of Management and Budget*. National Research Council, 2007.  
<http://www8.nationalacademies.org/onpinews/newsitem.aspx?RecordID=11811>.

Moreover, it is ironic that your proposal will require MSHA and OSHA to issue an Advance Notice of Proposed Rulemaking (ANPRM) soliciting public input, but you failed to follow this same mandate with respect to this proposal. It was developed without any opportunity for early public input.<sup>4</sup> In fact, the secrecy of this proposal resulted in a front-page story in the *Washington Post*<sup>5</sup> and a request from Senator Edward Kennedy (D-MA) and Congressman George Miller (D-CA) to be briefed by DOL about its proposal.<sup>6</sup>

We discuss three major flaws with the document: 1) altering the definition of a working life from 45 years to an average number of years, 2) calling for uncertainty analysis without providing any guidance that would actually improve the quality, reliability, or utility of such an analysis, and 3) taking regulatory action only where clinical adverse health outcomes have been demonstrated.

### **1) Altering the definition of a working life**

The proposed rule seeks to reduce the definition of a working life from as many as 45 years to an *average* number of years, justifying this move with data tables showing that most workers stay with the same employer for much less time than 45 years. While workers do change jobs, they are much less likely to change into a job that significantly reduces their risks. Individuals who learn a skilled trade like welding, for example, may indeed change employers over their careers, but most practice their welding trade for their entire working lives. Furthermore, an expert panel of the National Academies issued a report in 1994 that recommended against this unvalidated and unrealistic approach in their discussion of ambient exposures to the general public over a lifetime, notwithstanding the data that show multiple changes of residences over a lifetime.<sup>7</sup>

The attempt to weaken the definition of a working life is contrary to the health-protective frameworks mandated in the Occupational Safety and Health Act of 1970 and the Federal Mine Safety and Health Act of 1978, which specifically direct the Department of Labor to issue standards on toxic agents that assure workers' health is protected even if an employee "has regular exposure to the hazard...for the period of his working life."<sup>8</sup> Congress wanted OSHA and MSHA to set standards that would protect people who choose to work in the same industry for 45 years.

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<sup>4</sup> Monforton, C. Secret rule on OSHA risk assessment? The Pump Handle. July 8, 2008. <http://thepumphandle.wordpress.com/2008/07/08/secret-rule-on-osha-risk-assessment/>.

<sup>5</sup> Leonnig, CD. U.S. rushes to change workplace toxin rules. *Washington Post*. July 23, 2008; Page A01.

<sup>6</sup> Monforton, C. Congress demands briefing on Chao's mystery proposal for risk assessment. July 10, 2008. <http://thepumphandle.wordpress.com/2008/07/10/congress-demands-briefing-on-chaos-mystery-proposal-for-risk-assessment/>.

<sup>7</sup> NRC. *Science and Judgment in Risk Assessment*. 1994. p. 217.

<sup>8</sup> OSH Act of 1970, Section 6(b)(5); Mine Act of 1977, Section 101(a)(6)(A).

## **2) Calling for uncertainty analysis without providing any guidance that would actually improve the quality, reliability, or utility of such an analysis**

The proposal calls for a rigorous uncertainty analysis, but provides no clear guidance on how to conduct one. The NRC report criticizes this same failure in the OMB Risk Assessment Bulletin, saying,

“In the absence of clear guidance regarding the conduct of uncertainty analysis, there is a serious danger that agencies will produce ranges of meaningless and confusing risk estimates, which could result in risk assessments of reduced rather than enhanced quality and objectivity.”<sup>3</sup>

Because risk assessors must rely on imperfect and incomplete data, decisions are informed by various guidance documents that are publicly available and publicly documented, and have been publicly vetted. Reliance on guidance documents helps to ensure that evaluations are consistent across substances and as objective as possible. This proposal fails to provide any useful guidance for important questions such as what default assumptions agencies will use, how agencies will decide when available data is robust enough to move away from default assumptions, and how incomplete exposure data should be used to support dose-response estimates.

## **3) Taking regulatory action only where clinical adverse health outcomes have been demonstrated**

Finally, the draft regulatory text suggests the Department seeks to reserve its regulatory action for hazards associated solely with clinically apparent adverse health outcomes, by saying that, “The dose-response step determines a quantitative model that accounts for the relationship between a hazard and an adverse health outcome” (emphasis added). OMB in its Risk Assessment Bulletin was admonished for failing to specifically define the term “adverse.” The NRC (2007) panel wrote:

“The bulletin’s definition of *adverse effect* implies a *clinically* apparent effect, which ignores a fundamental public-health goal to control exposures well before the occurrence of any possible functional impairment of an organism. Dividing effects into ‘adverse and ‘nonadverse’ ignores the scientific reality that adverse effects may be manifest along a continuum.”<sup>3</sup> (emphasis in original)

By oversimplifying the risk assessment process, demanding an unachievable quantification of uncertainty, and defining adverse effects in a narrow manner that overlooks medical reality, the Department has created a proposed regulation that will hamper the OSHA and MSHA in their Congressionally-mandated duties to protect workers’ health from toxic agents.

In conclusion, this proposed rule will significantly weaken current risk assessment approaches without offering any improvements and will undermine worker health protections.

There are scores of workplace health and safety hazards for which the regulation needs to be updated, and hundreds more that have not yet been regulated. The Department of Labor should turn its attention and direct resources to such hazards as silica, diacetyl and beryllium – not to a deeply flawed rule that will make future efforts to safeguard the health of U.S. workers more difficult.

As industrial hygienists, physicians, epidemiologists, toxicologists, and other practitioners involved in workers' safety and health research and prevention programs, we urge you to withdraw this proposed rule.

Sincerely,

*Affiliations for identification purposes only, and do not constitute an endorsement on the part of the institution of information contained in this letter.*

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cc: The Honorable Edward M. Kennedy, Chairman, U.S. Senate Committee on Health,  
Education, Labor and Pensions

The Honorable George Miller, Chairman, House Committee on Education and Labor



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*Protect, Prevent, Live Well*

August 12, 2008

The Honorable Elaine L. Chao  
Secretary  
U.S. Department of Labor  
Suite S-2018  
200 Constitution Avenue, NW  
Washington, DC 20210

Dear Secretary Chao:

On behalf of the American Public Health Association (APHA), the nation's oldest and most diverse organization of public health professionals in the world, I write to express our opposition to Department of Labor's (DOL) proposed regulation that would significantly alter the preventive health framework embodied in the Occupational Safety and Health Act of 1970 (OSH Act) and the Mine Safety and Health Act of 1978 (Mine Act). The proposed "Requirements for DOL Agencies' Assessment of Occupational Health Risks," which is pending review at the White House's Office of Management and Budget, is contrary to the most fundamental public health principle of prevention.

Occupational diseases can best be prevented by reducing exposure levels of workers to toxic agents and processes. The DOL proposed rule seeks to alter the definition of a working life to an arbitrary *average* number of years -- a notion and that is wholly inconsistent with public health and risk science standards. The document also makes erroneous characterizations of uncertainty, risk, and adverse health effects, in direct opposition to recommendations made by the National Academies of Science (NAS) in their 2007 report.

The DOL draft proposal also would require that the Occupational Safety and Health Administration (OSHA) and the Mine Safety and Health Administration (MSHA) issue an Advanced Notice of Proposed Rulemaking for all health-based standards. This new mandatory step in the process will further delay protective rules, even those with well-understood adverse health effects, such as respirable coal mine dust and silica. Although the DOL is charged with worker health and safety protection, it has only issued one health standard over the last 10 years. The latest DOL proposal would only add steps to the rulemaking process, and thus delay health protections for workers even further.

APHA urges you to withdraw this proposed rule immediately.

Sincerely,

A handwritten signature in black ink that reads "Georges C. Benjamin". The signature is written in a cursive, flowing style.

Georges C. Benjamin, MD, FACP, FACEP (Emeritus)  
Executive Director